for-profit institutions); *Number of Respondents:* 20,000; *Total Annual Responses:* 4,589,433; *Total Annual Hours:* 351,046. (For policy questions regarding this collection contact Michael Forman at 410–786–2666.)

2. *Type of Information Collection Request:* Revision of a currently approved collection; *Title of Information Collection:* Administrative Requirements for Section 6071 of the Deficit Reduction Act; *Use:* State Operational Protocols should provide enough information such that: the CMS Project Officer and other federal officials may use it to understand the operation of the demonstration, prepare for potential site visits without needing additional information, or both; the State Project Director can use it as the manual for program implementation; and external stakeholders may use it to understand the operation of the demonstration. The financial information collection is used in our financial statements and shared with the auditors who validate CMS' financial position. The Money Follows the Person Rebalancing Demonstration (MFP) Finders File, MFP Program Participation Data file, and MFP Services File are used by the national evaluation contractor to assess program outcomes while we use the information to monitor program implementation. The MFP Quality of Life data is used by the national evaluation contractor to assess program outcomes. The evaluation is used to determine how participants' quality of life changes after transitioning to the community. The semi-annual progress report is used by the national evaluation contractor and CMS to monitor program implementation at the grantee level. The revisions aim to reduce the reporting burden by presenting a substantially revised and shorted version of the semi-annual progress report. The budget workbook has also been revised to combine two earlier reporting forms. *Form Number:* CMS–10249 (OMB control number: 0938–1053); *Frequency:* Yearly, quarterly, and semi-annually; *Affected Public:* State, Local, or Tribal Governments; *Number of Respondents:* 42; *Total Annual Responses:* 336; *Total Annual Hours:* 2,604. (For policy questions regarding this collection contact Todd Wilson at 410–786–3409.)

3. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Section 1115 Demonstration Projects Regulations at 42 CFR 431.408, 431.412, 431.420, 431.424, and 431.428; *Use:* This collection is necessary to ensure that states comply with regulatory and statutory requirements related to the development, implementation and evaluation of demonstration projects. States seeking waiver authority under Section 1115 are required to meet certain requirements for public notice, the evaluation of demonstration projects, and reports to the Secretary on the implementation of approved demonstrations. *Form Number:* CMS–10341 (OMB control number: 0938–1162); *Frequency:* Yearly and quarterly; *Affected Public:* State, Local, or Tribal Governments; *Number of Respondents:* 37; *Total Annual Responses:* 372; *Total Annual Hours:* 27,914. (For policy questions regarding this collection contact Tonya Moore at 410–786–0019.)

Dated: July 6, 2021.

William N. Parham, III,

Director, Paperwork Reduction Staff, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2021–14671 Filed 7–8–21; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–N–2347]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Food and Cosmetic Export Certificates

AGENCY: Food and Drug Administration, Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or we) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Submit written comments (including recommendations) on the collection of information by August 9, 2021.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be submitted to *https://www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under Review—Open for Public Comments'' or by using the search function. The OMB control number for this information collection is 0910–0793. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Domini Bean, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–5733, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Food and Cosmetic Export Certificates

OMB Control Number 0910–0793—Extension

Some countries may require manufacturers of FDA-regulated products to provide certificates for products they wish to export to that country. Accordingly, firms exporting products from the United States often ask FDA to provide such a ''certificate.'' In many cases, foreign governments are seeking official assurance that products exported to their countries can be marketed in the United States, or that they meet specific U.S. requirements. In some cases, review of an FDA export certificate may be required as part of the process to register or import a product into another country. An export certificate generally indicates that the particular product is marketed in the United States or otherwise eligible for export and that the particular manufacturer has no unresolved enforcement actions pending before, or taken by, FDA.

FDA's Center for Food Safety and Applied Nutrition (CFSAN) issues export certificates for human food and cosmetic products. Interested persons may request a certificate electronically via the CFSAN Export Certification Application and Tracking System (CFSAN eCATS) or Certificate Application Process (CAP), components of the FDA Industry Systems, or by contacting CFSAN for assistance. Health certificates are the exception and are requested via email. To facilitate the application process, we have eliminated paper-based forms. For food products, respondents are able to identify facilities using their Food Facility Registration, an FDA Establishment Identifier number, or a Data Universal Numbering System number. The system uses these identifiers to locate and auto-populate name and address information, eliminating the need for users to manually enter this information and reducing the time to complete the application. For some applications, respondents can also upload product information via a spreadsheet, which reduces the time needed to enter

product information, particularly for applications that include multiple products.

All information is entered using electronic Forms FDA 3613d, 3613e, and 3613k and used to evaluate certificate requests. The eCATS Module is Form FDA 3613k, where Form FDA 3613e is the Certificate of Free Sale (*https://www.fda.gov/food/food-export-certificates/online-applications-export-certificates-food*). All ''forms'' are electronic and part of the eCATS or CAP portal accessed via *https://www.access.fda.gov.* To view representations of the forms, you have to download the instructions, which are accessible from the following links: *https://www.fda.gov/cosmetics/cosmetics-exporters/online-applications-export-certificates-cosmetics* and *https://www.fda.gov/food/food-export-certificates/online-applications-export-certificates-food.*

While burden associated with information collection activities for export certificates issued for other FDA-regulated products is approved under OMB control number 0910–0498, this collection specifically supports export certificates issued by CFSAN. Also, because we have eliminated paper-based forms, respondents who require assistance with completing export certificate applications online may contact CFSAN directly by email (*CFSANExportCertification@fda.hhs.gov*) or telephone (240–402–2307). Instructions for requesting export certificates for cosmetics (Form FDA 3613d) are available online at *https://www.fda.gov/cosmetics/cosmetics-exporters/online-applications-export-certificates-cosmetics* and instructions for requesting export certificates for food (Forms FDA 3613e and 3613k) are available online at *https://www.fda.gov/food/food-export-certificates/online-applications-export-certificates-food.*

Description of Respondents: The respondents to this collection of information are firms interested in exporting U.S.-manufactured human food and cosmetic products to foreign countries that require export certificates.

In the **Federal Register** of March 16, 2021 (86 FR 14452), we published a 60-day notice requesting public comment on the proposed collection of information. We received one comment offering general support for our cosmetic export certificate program. The comment also recommended FDA consider providing certificates that allow exporters to use an exemption from requirements in China for animal testing for certain imported cosmetic products. We appreciate the comment and continue to seek ways to increase the utility of the information collection as our limited resources permit. At the same time, the comment did not suggest we revise the burden we attribute to the associated information collection activity.

We estimate the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Type of respondent	Form No. [2]	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response (in hours)	Total hours
Cosmetics	FDA 3613d	113	3	339	0.5 (30 minutes)	170
Food	FDA 3613e, 3613k	468	9	4,212	0.5 (30 minutes)	2,106
Total						2,276

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] All forms are submitted electronically via FDA Industry Systems.

Based on a review of the information collection since our last OMB approval, we have reduced our burden estimate. The burden estimate has been lowered due to a reduced number of respondents. We base our estimates on our experience with certificate applications received in the past 3 fiscal years.

Dated: July 2, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2021–14650 Filed 7–8–21; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2021–Z–0025]

Requests for Proposals for Insulin Reimportation and Personal Prescription Drug Importation; Withdrawal

AGENCY: Food and Drug Administration (FDA), Department of Health and Human Services (HHS).

ACTION: Notice; withdrawal.

SUMMARY: The Department of Health and Human Services (Department or HHS) is announcing the withdrawal of a notice published in the **Federal Register** on January 21, 2021, entitled ''Requests for Proposals for Insulin Reimportation and Personal Prescription Drug Importation.'' HHS also withdraws the requests for proposals issued on its website on September 24, 2020, and revised on January 13, 2021, and ends the period for submission of proposals in response to the requests for proposals.

DATES: The notice published in the **Federal Register** on January 21, 2021, at 86 FR 6343, is withdrawn as of July 9, 2021.

FOR FURTHER INFORMATION CONTACT: Katelyn Mineo, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6222, Silver Spring, MD 20993, 301–796–1054.

SUPPLEMENTARY INFORMATION: On September 24, 2020, HHS issued two requests for proposals for the reimportation of insulin and the personal importation of prescription drugs (collectively, the RFPs) and posted related ''Frequently Asked Questions'' documents (FAQs) on its website. On January 21, 2021, HHS published a notice in the **Federal Register** entitled ''Requests for Proposals for Insulin Reimportation and Personal Prescription Drug Importation'' (the HHS Notice) (86 FR 6343). The HHS Notice referred to revised versions